

## II. REMARKS

### **1. Formal Matters**

#### *a.) Action Summary*

According to the Office Action, claims 21-31 stand pending in the application. Claims 21-31 stand rejected. By the amendment presented above, pending claims should now be 21-54.

#### *b.) Comments on the Examiner's Reasons for Allowance*

The Examiner is thanked for acknowledging that WO2004/070352 does not qualify as 35 USC 102(e) prior art.

#### *c.) Antecedent Basis for claims 39, 40, 49, 50, 60, 61 and 62.*

At page 6 of the present Office Action claims 21-31 are rejected under the written description requirement because Applicants' allegedly lack 'possession' of the claimed subject matter. The rejection reasons that claims 21-31 lack written description because claims 39, 49, 60, 40, 50, 61 and 62 cannot be found in the amendment presented with the request for continued examination filed on December 12, 2006.

While it is true that any reference to claims 39, 40, 49, 50, 61 and 62 in the remarks presented in the submission dated December 12, 2006 is erroneous since these claims are not found in the amendment, it is unclear how this fact causes unrelated claims 21-31 to lack proper written description. To be clear on this point, claims 21-31 do not refer to claims 39, 40, 49, 50, 61 or 62. Perhaps the rejection was intended to be directed to claims 39, 40, 49, 50, 61 and 62 (and not 21-31) since they were not presented but nevertheless discussed in the remarks. Regardless, as will be discussed in more detail below, Applicants submit that claims 21-31 are properly supported by the written description. Accordingly, it is believed that this rejection should be withdrawn as erroneous.

### **2. Comments on the Amendment to the Claims**

Claims 1-20 were previously canceled. Claims 21-31 were presented with the amendment submitted on December 12, 2006.

Claim 21 is amended to change 'derived' to 'generated'. This change is believed to be cosmetic but is nevertheless supported throughout the specification but in particular at page 27, line 13 to page 28, line 23. Claims 21 and 31 are amended to delete the text: "*wherein the fragment ions are either positively or negatively charged*". It is believed that this is an inherent property of a fragment ion existing in a mass spectrometer and accordingly need not be expressly stated. Accordingly, it is believed that these amendments do not change claim scope.

Additionally, new claims 32-54 are now presented. These claims are presented to more distinctly claim the subject matter for which applicants seek letters patent. Antecedent basis for these new claims can be found throughout the specification as filed but in particular in the specification as follows:

*Independent claims:*

- i) Claims 32, 37, 42, 51: Page 20, line 11 to page 24, line 11.
- ii) Claims 47 and 52: Page 23, line 18 to page 24, line 11.
- iii) Claims 53 and 54: Page 22, lines 20-25.

*Dependent claims:*

- i) Claims 33, 38, 43 & 48: Page 4, lines 8-24.
- ii) Claims 34, 39, 44 & 49: Page 22, lines 20-25.
- iii) Claims 35, 40, 45 & 50: Page 26, line 22 to page 27, line 10.
- iv) Claims 36, 41 & 46: Page 23, line 18 to page 24, line 11. as well as page 26, line 22 to page 27, line 10.

New matter is not believed to have been added.

### **3. Comments on the Rejections For Lack of Written Description**

a.) *Rejection of claims 21-31 made without reference to claims 39, 40, 49, 50, 61 and 62*

At pages 2-6 of the Office Action, the rejection of claims 21-31 for lack of written description is presented. In particular, it is asserted that Applicants lack 'possession' of the claimed subject matter. Applicants traverse this rejection.

b.) *The Law related to Written Description*

There is a strong presumption that an adequate written description of the claimed invention is present when the application is filed." M.P.E.P. § 2163 (I)(A). The examiner, therefore, must therefore have a reasonable basis to challenge the adequacy of the written description". M.P.E.P. § 2163.04 In rejecting a claim, the examiner must set forth express findings of fact which support the lack of written description conclusion..." M.P.E.P. § 2163.04(I).

"The analysis of whether the specification complies with the written description requirement calls for the examiner to compare the scope of the claim with the scope of the description to determine whether applicant has demonstrated possession of the claimed invention. Such a review is conducted from the standpoint of one of skill in the art at the time the application was filed...." M.P.E.P. § 2163(II)(A)(2) **"Information which is well known in the art need not be described in detail in the specification."** *Id.* An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. M.P.E.P. § 2163(I).

c.) *Rebuttal*

In a nut shell, the rejection argues that there is insufficient written description to support use of "analyte" in the claimed subject matter. Although presented as a rejection for lack of written description because Applicants allegedly lack 'possession' of analytes that can be "*conjugated to N-methyl-piperazine acetic acids*" (OA at page 4), a fair read of the supporting argument demonstrates that the rejection is really arguing breath. Regrettably, this angst over breath of the claimed subject matter is misguided and prejudicial.

Applicants first note that this is a new rejection. Former claims 7-20, **which were allowed**, used substantially the same claim language as the presently pending claims in, for example, claim 21 (compare with former claim 7). Accordingly, it is remarkable that this rejection is now presented for the first time. Reference is also made to MPEP § 707.07.

Regardless, by its reliance on quotations from: "*California v. Eli Lilly & Co., 43 USPQ2d 1398*" and the statement: "*It must not be forgotten that the MPEP states that if a biomolecule is described only by functional characteristics, without any disclosed*

*correlation between function and structure of the sequences, it is not sufficient characteristics for written description purposes, even when accompanied by a method of obtaining the claimed sequence"* (OA at page 5), it would seem that the Office considers the analyte to be that which has been invented. IT IS NOT THE ANALYTE THAT IS BEING INVENTED!

A review of the claims reveals that it is not the nature of the analyte which bestows inventiveness to the claimed subject matter. Rather, it is the unique nature of the linked N-methyl-piperazine acetic acid moiety (or fragment ions derived therefrom in a mass spectrometer) which bestows inventiveness on the claimed subject matter. Thus, these arguments supporting the rejection are misguided. The rejection is also prejudicial since it precludes Applicants from generically claiming subject matter related to various types of analyte molecules of interest to the ordinary practitioner labeled with the unique N-methyl-piperazine acetic acid moieties developed. Since analytes are not being invented, any analyte molecule of interest, that can be labeled with the inventive labeling reagents comprising the N-methyl piperazine acetic acid (described herein), would be within the knowledge of one of skill in the art, and thus, need not be described in detail in the specification. M.P.E.P. § 2163(II)(A)(2)

Moreover, Applicants demonstrate possession of the invention: "... by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. M.P.E.P. § 2163(I) Analyte is defined, *inter alia*, in the specification at page 4 as: "a molecule of interest that may be determined". The specification further describes methods for labeling said analytes with the disclosed labeling reagents comprising the N-methyl piperazine acetic acid moiety and then analyzing fragment ions of said labeled analytes in a mass spectrometer. As noted in the Office Action at page 4, examples of analytes expressly described in the specification include: "...peptides, proteins, nucleic acids, carbohydrates, lipids, steroids and small molecules [with a molecular weight or less than 1500 Daltons (Da)]". Thus, it is clear that the specification uses words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. From this standpoint compliance with the written description requirement is self-evident. Accordingly, reconsideration and withdrawal of the rejection of claims 21-31 under 35 U.S.C. § 112, first paragraph discussed at pages 2-6 of the present Action is respectfully requested.

d.) *Rejection of claims 21-31 made with reference to claims 39, 40, 49, 50, 61 and 62*

At page 6 of the Office Action, claims 21-31 are rejected under 35 U.S.C. § 112, first paragraph. This rejection is discussed in section 1c (Formal Matters) above. Respectfully, it is believed that this rejection was unintended and based upon some erroneous discussion in the paper submitted by Applicants on December 12, 2006. If the Examiner believes that the rejection is still appropriate, clarification is requested particularly in view of the discussion and amendment to the claims presented above.

#### **4. Comments on Claims 53 and 54**

Notwithstanding the foregoing, new claims 53 and 54 do not make reference to the analyte molecule. Accordingly, they cannot be said to suffer the defect for which claims 21-31 have been rejected in the present Office Action. Accordingly it is believed that claims 53 and 54 are allowable notwithstanding any arguments of record.

### III. INTERVIEW

It is believed that the application is in condition for allowance. If the Examiner believes a telephonic or personal interview would advance the prosecution of the subject application, the Examiner is invited to contact attorney Gildea during business hours at the telephone or facsimile numbers listed below.

### IV. FEES

A petition under 37 C.F.R. § 1.136(a) for a three (3) month extension, and authorization to deduct the appropriate fee from Deposit Account No. 01-2213 accompanies said petition.

According to the fee calculation sheet in PAIR dated June 8, 2006, fees for 20 total claims and 3 independent claims have thus far been paid to the Office with respect to the present application. Upon entry of this amendment, this application will contain 34 total claims and 10 independent claims. The following calculations indicate that a fee of \$2,100.00 is due the Office for entry of this amendment and for the consideration of the amended set of claims.

Total Claims	-	Claims Paid	=	Claims to be Paid	x \$50.00	Totals
34	-	20	=	14	\$ 700.00	\$ 700.00
Total Ind. Claims		Ind. Claims Paid		Ind. Claims to be Paid	x \$ 200.00	
10		3		7	\$ 1,400.00	\$ 1,400.00
					Total Due Office	\$ 2,100.00

The Office is hereby authorized to deduct the fee due, believed to be \$2100.00, for entry of this amendment set forth herein from Deposit Account 01-2213 (Order No. BP0309US-CP1). No other fees are believed to be due to The Office for consideration of this paper. If however, The Office determines that any fee is properly due for its consideration of this paper, authorization is hereby granted to charge any required fee associated with the filing or proper consideration of this paper to Deposit Account 01-2213 (Order No. BP0309US-CP1).

#### V. CORRESPONDENCE/CUSTOMER NUMBER

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IF NOT ALREADY DONE, PLEASE ASSOCIATE THIS CASE WITH CUSTOMER NUMBER

**23544**

Respectfully submitted  
on behalf of Applicants,

July 2, 2007  
Date

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